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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/939,518 | 08/24/2001 | Mark J. Jaroszeski | 93004 | 2429 |

9355 7590 08/26/2003

ALLEN, DYER, DOPPELT, MILBRATH & GILCHRIST, PA
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ORLANDO, FL 32802-3791

[REDACTED] EXAMINER

ANGELL, JON E.

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1-1635 | 18 |

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/939,518 | JAROSZESKI ET AL. | |
| | Examiner | Art Unit | |
| | J. Eric Angell | 1635 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 16 June 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,2,4,6,8,10-12,14,16,18 and 20-36 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) 21-29 and 31-36 is/are allowed.

6) Claim(s) 1,2,4,6,8,10-12,14,16,18 and 20 is/are rejected.

7) Claim(s) 30 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/16/03 has been entered.
2. The amendment filed 6/16/03 has been entered. Claims 1, 2, 4, 6, 8, 10-12, 14, 16, 18 and 20-36 are currently pending in the application and are examined herein.
3. Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

5. Claims 1, 2, 4, 6, 8, 10-12, 14, 16, 18 and 20 remain rejected under 35 U.S.C. 102(b) as being anticipated by Hofmann et al. (U.S. Patent 6,055,453, published April 25, 2000), for the reasons of record, summarized below.

Hofmann teaches a method for facilitating a delivery of a desired molecule, here nucleic acids, antisense nucleic acids, Ribozymes, polypeptides, and polynucleotides (such as expression

vectors) encoding metabolic enzymes and proteins(see col. 12, lines 14 and 34; col. 13, lines 13, 24 and 31-31), into a target tissue comprising a cell; and applying a substantial continuous low-level electric field to the target tissue for a duration sufficient to effect a change in porosity of the cell of the target tissue sufficient to facilitate entry of a desired molecule into an interior of a cell (for example see col. 1, lines 6-13; col. 10, lines 3-56; and col. 11, lines 63-65);

Wherein the low-level electric field has a field strength comprising 10V/cm-20kV/cm and for a duration of $10\mu\text{s}$ -**100ms** (Emphasis added; see col. 10, lines 3-41);

Wherein the electric field comprises multiple square pulse waveforms (see col.10, line 55-56);

Wherein the introducing step comprises needle injection (i.e. syringe) (see col. 13, lines 31-45 and);

Wherein the target tissue is skin, tumor, muscle, ovary, prostate, lung, heart, kidney, colon, testis, melanoma, etc. (see col. 14, lines 10-30).

And wherein the method further comprises a means for constructing a plasmid comprising a DNA and cDNA encoding a molecule of interest (see col. 12, line 61-col. 13, line 11).

Hofmann also teaches a system comprising a means for facilitating the delivery of a desired molecule, here nucleic acids, antisense nucleic acids, Ribozymes, polypeptides, and polynucleotides (such as expression vectors) encoding metabolic enzymes and proteins(see col. 12, lines 14 and 34; col. 13, lines 13, 24 and 31-31), into a target tissue comprising a cell; and a means for applying a substantial continuous low-level electric field to the target tissue for a duration sufficient to effect a change in porosity of the cell of the target tissue sufficient to

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facilitate entry of a desired molecule into an interior of a cell (for example see col. 1, lines 6-13; col. 10, lines 3-56; and col. 11, lines 63-65);

Wherein the low-level electric field has a field strength comprising 10V/cm-20kV/cm and for a duration of $10\mu\text{s}$ -**100ms** (Emphasis added; see col. 10, lines 3-41);

Wherein the electric field comprises multiple square pulse waveforms (see col.10, line 55-56);

Wherein the means for introducing the molecule comprises needle injection (i.e. syringe) (see col. 13, lines 31-45 and);

Wherein the target tissue is skin, tumor, muscle, ovary, prostate, lung, heart, kidney, colon, testis, melanoma, etc. (see col. 14, lines 10-30);

And wherein the system comprises a means for constructing a plasmid comprising a DNA and cDNA encoding a molecule of interest (see col. 12, line 61-col. 13, line 11).

Response to Arguments

6. Applicant's arguments filed 6/16/06 have been fully considered but they are not persuasive.

7. Applicants argue that the Hofmann describes applying a series of pulses to facilitate the entry of the molecules into the cells. Applicants contend that Hoffman does not contemplate a single low-level electric field that is applied for a duration of 100ms to 20 minutes in order to affect the entry of a molecule into a cell (see pages 11-12 or response filed 6/16/03).

8. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a single low-

level electric field that is applied for a duration of 100ms to 20 minutes) are not limitations of the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

It is respectfully pointed out that that claim 1 recites, “A method for facilitating the delivery of a desired molecule into a target tissue comprising the steps of... applying an electric field to the target tissue, the application of the electric field consisting of a single continuous low-level electric field applied for a duration of 100ms to 20 minutes...” (Emphasis added). Applicants are respectfully reminded that the term “comprises” is considered open language and does not limit the claims to a method consisting only of the recited steps and no other steps. Since the preamble of the claims indicates that the method comprises applying the described electric field, the claim encompasses a method comprising applying the described electric field more than one time. It is noted that changing the language of the preamble to a method for facilitating the delivery of a desired molecule into a target tissue consisting of the steps indicated, would obviate this rejection.

Miscellaneous

The rejection of claims under 35 USC 112, first paragraph; 35USC 102(a) as being anticipated by Lucas; 35USC 102(a) as being anticipated by Heller; 35USC 102(a) as being anticipated by Betten; and 35USC 102(b) as being anticipated by Mir are withdrawn in view of the amendment, applicants arguments, and/or the cancellation of claims.

Claim Objections

9. Claim 30 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 30 depends on claim 29, drawn to a system for facilitating the delivery of a desired molecule into a target tissue comprising... applying a low-level electric field to the target tissue for a duration of 200ms to 20 minutes..." (Emphasis added). However, claim 30 is drawn to the system of claim 29 wherein the electric field is applied for a duration of 100ms to 100sec." (Emphasis added). It is respectfully pointed out that 100ms-100sec overlaps with, but is not within the range of 200ms-20mins set forth in claim 29. Therefore, claim 30 fails to further limit claim 29. It is noted that amending claim 30 to recite 200ms to 100sec would obviate this objection.

Allowable Subject Matter

10. Claims 21-29, 31-36 are allowed because the claims are limited to a system and method comprising applying an electric field having a duration of 200ms to 20 mins.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

J. Eric Angell
Patent Examiner
AU 1635



DAVE T. NGUYEN
PRIMARY EXAMINER